MODEL STANDING ORDERS

Meningococcal Quadrivalent Conjugate Vaccine (MCV4)

These model standing orders are current as of February 2006. They should be reviewed carefully against the most current recommendations and may be revised by the clinician signing them.

MCV4 is recommended (in individuals 11-55 years of age only) for:

- Routine vaccination of adolescents:
 - Young adolescents at their routine adolescent visit (11-12 years of age);
 - Adolescents at high school entry (or 15 years of age, whichever comes first) for the next 3 years.
- Routine vaccination of other persons at increased risk for meningococcal disease:
 - College freshmen and other newly enrolled college students living in dormitories
 - Microbiologists routinely exposed to isolates of *N. meningitidis*
 - Military recruits
 - Persons who travel to or reside in countries where meningococcal disease is hyperendemic or epidemic
 - Persons with terminal complement deficiency
 - Persons with functional (i.e., sickle cell disease) or anatomic asplenia
- Outbreak Control:
 - MCV4 may be used (for individuals 11-55 years of age **only**) as an adjunct to chemoprophylaxis in the control of outbreaks caused by the vaccine serogroups in populations delineated by community or institutional boundaries, where the number of cases exceeds defined thresholds.

MCV4 can be <u>considered</u> (in individuals 11-55 years of age *only*) for:

- Persons with HIV infection (MCV4 preferred, meningococcal polysaccharide [MPSV4] acceptable)
- Persons who wish to reduce their risk of disease.

Please note: MCV4 is currently licensed for use in individuals 11-55 years of age ONLY. MCV4 is the preferred formulation for individuals in this age group. However, administration of MPSV4 is acceptable.

Vaccine	Age Group	Dose	Route
MCV4	11-55 years	0.5 mL	IM
MSPV4	\geq 2 years	0.5 mL	SC

ORDER:

- 1. Provide patient, parent or legal representative with a copy of the Vaccine Information Statement (VIS) and answer any questions.
- 2. Screen for contraindications according to Table 1.
- 3. Administer a single dose of MCV4 vaccine 0.5 mL intramuscularly (IM) in the deltoid using a 1-2 inch needle. Administer IM vaccines at a 90⁰ angle, using a 22-25 gauge needle. Consult Table 2 for a summary of the recommendations by age group and Table 4 for guidelines on revaccination.

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Always check the package insert prior to administration of any vaccine.

- Needle length depends on the vaccine recipient's weight (1 inch for females < 70 kg; 1.5 inches for females 70-100 kg; 1 to 1.5 inches for males ≤ 120 kg; and 2 inches for males > 120 kg and females > 100 kg).
- 4. Administer MCV4 vaccine simultaneously with all other vaccines indicated, but at a different site.*
- 5. If possible, observe patient for an allergic reaction for 15 20 minutes after administering vaccine.
- 6. Facilities and personnel should be available for treating immediate hypersensitivity reactions.
- 7. Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967, or via the VAERS website: http://vaers.hhs.gov.
- 8. Please see the MIP document, *General Protocols for Standing Orders*, for further recommendations and requirements regarding vaccine administration, documentation and consent.

* Note on simultaneous administration of MCV4:

- Simultaneous administration of MCV4 with other diphtheria-containing vaccines is preferred in order to decrease any theoretic possibility of increased local reactions.
- If simultaneous administration of MCV4 with other diphtheria-containing vaccines is not feasible, inactivated vaccines can be administered at any time before or after a different inactivated or live vaccine. Tdap (or Td) and MCV4 vaccines (which all contain diphtheria toxoid) can be administered using any sequence.

Table 1. Contraindications and Precautions to MCV4

Valid Contraindications to MCV4	Invalid Contraindications (MCV4 should be administered)
Anaphylactic reaction to previous dose of MCV4, diphtheria toxoid, latex, or to any other	Mild illness with or without low-grade fever
component of the vaccine (see package insert for specific components) ¹	Local reaction to a previous dose of MCV4
for specific components)	Non-anaphylactic allergy to any vaccine component
Precautions to MCV4:	Pregnancy ²
Moderate or severe illness with or without fever (temporary precaution)	Breast feeding
	Current antimicrobial therapy

¹ Persons with a history of anaphylaxis to a vaccine component, but who are at risk for meningococcal disease, should be referred to a health care provider for evaluation and possible administration of MCV4 vaccine.

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² As with other inactivated vaccines, pregnancy is not a contraindication to MCV4. Pregnancy testing prior to vaccination is not necessary. MCV4 is safe and immunogenic among nonpregnant persons 11-55 years of age, but no data are yet available on the safety of MCV4 during pregnancy. According to the ACIP's general recommendations on immunization, inactivated vaccines can and should be given to pregnant women, if indicated (http://www.cdc.gov/mmwr/PDF/rr/rr5102.pdf).

Table 2. Recommendations for the Use of Meningococcal Vaccines among Persons Not Vaccinated Previously

Age group (yrs)

Population group	<2	2-10	11-19	20-55	>55
General population	Not recommended	Not recommended	A single dose of MCV4* is recommended at age 11 – 12 years (at preadolescent assessment visit) or at high school entry (at approximately age 15 years	Not recommended	Not recommended
Groups at increased risk College freshmen living in dormitories Certain travelers Certain microbiologists Certain populations experiencing outbreaks of meningococcal disease ** Military recruits Persons with increased susceptibility ††	Not usually recommended [†]	A single dose of MPSV4	A single dose of MCV4 is preferred (MPSV4 is an acceptable alternative)	A single dose of MCV4 is preferred (MPSV4 is an acceptable alternative)	A single dose of MPSV4

^{*} Meningococcal conjugate vaccine.

¶ Microbiologists who are routinely exposed to isolates of *N. meningitidis* should be vaccinated.

(Adapted from: Table 6. CDC. Prevention and control of meningococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2005;54(No.RR-7):14.)

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[†] Meningococcal polysaccharide vaccine (MPSV4) (2 doses, 3 months apart) can be considered for children age 3 – 18 months to elicit short-term protection against serogroup A disease (a single dose should be considered for children age 19 – 23 months).

Persons who travel to or in areas where *N. meningitidis* is hyperendemic or epidemic are at increased risk of exposure, particularly if contact with the local population will be prolonged. Vaccination is especially recommended to those visiting the "meningitis belt" of sub-Saharan Africa during the dry season (December–June), and vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj. Advisories for travelers are available at http://www.cdc.gov/travel/outbreaks.htm, http://www.cdc.gov/travel/, or by calling CDC's Travelers' Health Hotline at 877-FYI-TRIP (toll-free).

^{**} The use of vaccination in outbreak settings has been described previously (**Source:** CDC. Control and prevention of meningococcal disease, and Control and prevention of serogroup C meningococcal disease: evaluation and management of suspected outbreaks: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1997;46 [No.RR-5]:13–21).

^{††} Includes persons who have terminal complement component deficiencies and persons with anatomic or functional asplenia.

Table 3. Guidelines on Revaccination with MCV4

For persons previously vaccinated with MPSV4, revaccination with MCV4 or MPSV4 *may* be indicated for those who remain at high risk for infection (e.g., asplenia, persons who reside in areas in which disease is endemic, living in a dormitory for the *first time*).

- Consider revaccination of children first vaccinated when they were <4 years of age after 2-3 years, if they remain at increased risk (e.g., residing in an endemic country).
- The need for revaccination of older children and adults with MCV4 has not been determined.
- If an indication exists, consider revaccination with MCV4 *once*, 5 years* after the first dose of MPSV4.
 - * Some sources recommend considering revaccination after a 3-year interval. Examples of when the 3-year interval might be used include, imminent travel to an area experiencing an outbreak of meningitis or in the case of an HIV-infected individual. For additional information on these groups, see Recommendations for Routine Vaccination of Other Persons at Increased Risk of Meningococcal Disease (page 1).
- For persons 11-55 years of age revaccination with MCV4 is preferred, but MPSV4 is acceptable.
- Continued attendance at college or continued residence in a dormitory is **not** an indication for revaccination in the absence of other indications (e.g., travel, asplenia).
- MCV4 is expected to provide longer protection than MPSV4. We anticipate that more data will become available over the next 5 years to guide recommendations on revaccination for persons who were previously vaccinated with MCV4.
 - However, selective revaccination with MPSV4 is recommended every 3-5 years if the person continues to remain at increased risk (e.g., an individual ≥56 years of age working as a microbiologist routinely exposed to isolates of *N. meningitidis*).

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References:

American Academy of Pediatrics. Active Immunization. Immunization in Special Clinical Circumstances. Meningococcal Infections. Standards for Child and Adolescent Immunization Practices (Appendix II). In: Pickering LK, ed. *Red Book: 2003 Report of the Committee on Infectious Diseases.* 26th ed. Elk Grove Village, IL. American Academy of Pediatrics 2003: 7-53, 66-93, 430-436, 795-798.

CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP). MMWR 2002; 51 (No.RR-2):1-35.

CDC. Guide to contraindications to vaccinations. U.S. Department of Health and Human Services, September 2003.

CDC. Prevention and control of meningococcal disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2005;54 (No.RR-7):1-21.

National Vaccine Advisory Committee. Standards for child and adolescent immunization practices. Pediatrics 2003;112:958-963.

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